

## **REMARKS**

### **I. Amendments**

By this amendment, claim 1 has been amended and claim 30 had been cancelled.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No amendment of inventorship is necessitated by this amendment.

### **II. Discussion of the Second Supplemental Information Disclosure Statement**

A Second Supplemental Information Disclosure Statement, Form 1449, seven references, a Statement under 37 CFR Sec. 1.97(e) and the fee set forth in 37 CFR Sec. 1.17(p) accompany this response. Consideration of the pending claims in light of the references is respectfully requested.

### **III. Discussion of the Rejection under 35 U.S.C. Sec. 102(e)**

Claims 1-7, 9, 11-19, 21, 22, 24, 31-33, 36, 38-44 and 46-49 have been rejected under 35 U.S.C. Sec. 102(e) as allegedly anticipated by Shimizu *et al.*, U.S. Patent No. 5,824,339.

The cited reference is directed to effervescent compositions including (a) enteric coating layer, water-soluble polymer and active agent; (b) an effervescing component and (c) an auxilliary effervescing agent.

By contrast, the present invention is directed to orally disintegrable tablets or fine granules including (a) enteric coating agent, sustained release agent and active agent; and (b) an additive, as set forth in independent claims 1 and 32.

By this amendment, claim 1 has been amended to include the limitation of claim 30.

Claim 30 was not subject to the present rejection. Therefore Applicants assert that the aspect of their invention, as set forth in independent claim 1 as amended is not anticipated by the cited reference.

Claim 30 has been cancelled. Claims 2-7, 9, 11-19, 21, 22, 24 and 31 depend upon claim

1. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference, for the reason provided above.

Independent claim 32 recites an enteric coating layer including an enteric coating agent and a sustained release agent. The cited reference is not directed to this type of enteric coating layer. No examples of this type are provided, and no guidance on how to make this type of granule is given. Therefore the cited reference does not anticipate the aspect of Applicants' invention set forth in claim 32.

Claims 33, 36, 38-44 and 46-49 depend upon claim 32. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference, for the reason provided above.

Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 102(e).

#### **IV. Request for a Clarification of the Status of the Former Rejection under 35 U.S.C. Sec. 102(a)**

Claims 32-36 and 38-49 had been rejected under 35 U.S.C. Sec. 102(a) as allegedly anticipated by Shimizu *et al.*, U.S. Patent No. 5,824,339, in the Office Action dated September 4, 2002. That Office Action also stated that the rejection would be reconsidered and withdrawn, provided that Applicants submit translations of the priority documents for the present

application. In accordance with that request, certified copies of the five translated priority documents were forwarded with Applicants' response of December 3, 2002.

In the communication dated March 3, 2003, there was no indication as to the Examiner's receipt of or consideration of the translations of the five priority documents, or an indication as to whether this rejection has been maintained or has been overcome. The Examiner is requested to state that the rejection has been overcome for the record.

**V. Request for a Clarification of the Status of the Former Rejection under 35 U.S.C. Sec. 103(a) over Shimizu *et al.* '339**

Claims 31-36 and 38-49 had been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious in light of Shimizu *et al.*, U.S. Patent No. 5,824,339, in the Office Action dated September 4, 2002.

As an initial matter, Applicants believe that claim 31 has been included in this rejection only due to typographical error. While the other rejected claims depend upon claim independent claim 32, claim 31 depends upon claim 1. The Applicants request that the Examiner specifically state why claim 31 is rejected, should the rejection be maintained, as Applicants cannot understand how claim 31 could be rejected on the basis of the cited art if independent claim 1 and the other claims depending upon claim 1 are free of the cited art.

In Applicants' response dated December 3, 2002, they cancelled claims 34, 35 and 45. Claims 33, 36, 38-44 and 46-49 depend upon claim 32. As indicated in Sec. III above, the enteric coating layer recited in claim 32 including an enteric coating agent and a sustained release agent is not taught or suggested by the cited reference. For this reason, Applicants submit that

neither independent claim 32 nor the more specific dependent claims are rendered obvious by the cited reference.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) rejection over Shimizu *et al.*, U.S. Patent No. 5,824,339.

**VI. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Shimizu *et al.* '339 in view of Shimizu *et al.*, '904**

Claims 1-9 and 11-30 had previously been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious in light of Shimizu *et al.*, U.S. Patent No. 5,824,339 in view of Shimizu *et al.*, U.S. Patent No. 6,299,904.

In response to the Applicants' assertion that the '904 reference is not proper art, the Examiner indicated in the last paragraph of page 6 of the Office Action, that the foreign priority date of the '904 reference (5/27/97) was relied upon. As the Applicants understand it, it is *simply not possible* to rely on the foreign priority date of the cited art (pre-AIPA or post-AIPA). If the Examiner chooses to maintain the rejection, specific support in the law which would allow the use of the 5/27/97 date should be cited. It is Applicants' firm belief that the use of the Japanese filing date of the Japanese priority application of the presently cited U.S. '904 patent to classify the '904 patent as proper art for the present application is impermissible.

Applicants also note that claims 8 and 20 have previously been cancelled, claim 30 has presently been cancelled; and that claim 31 is also dependent upon claim 1.

The arguments made in Sec. III above with respect to the '339 reference are hereby incorporated by reference into this section, to overcome the obviousness rejection.

Since the '904 reference is not proper art, the teachings of the '904 reference cannot be combined with the teachings of the '339 reference to render the claims obvious.

Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Shimizu *et al.* '339 in view of Shimizu *et al.* '904.

**VII. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Shimizu *et al.* '339 in view of Kamada**

Claims 31-33, 36, 38-44 and 46-49 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious in light of Shimizu *et al.*, U.S. Patent No. 5,824,339 in view of Kamada, EP 0 452 862.

As an initial matter, Applicants believe that claim 31 has been included in this rejection only due to typographical error. While the other rejected claims depend upon claim independent claim 32, claim 31 depends upon claim 1. The Applicants request that the Examiner specifically state why claim 31 is rejected, should the rejection be maintained, as Applicants cannot understand how claim 31 could be rejected on the basis of the cited art if independent claim 1 and the other claims depending upon claim 1 are free of the cited art.

The arguments made in Sec. III above with respect to the '339 reference are hereby incorporated by reference into this section, to overcome the obviousness rejection.

The deficiencies of Shimizu *et al.* '339 are not cured by Kamada.

Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Shimizu *et al.* '339 in view of Kamada.

**VIII. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Shimizu *et al.* '339 and Kamada in view of Shimizu *et al.*, '904**

Claims 1-7, 9, 11-19 and 21-30 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious in light of Shimizu *et al.*, U.S. Patent No. 5,824,339 and Kamada, EP 0 452 862, in view of Shimizu *et al.*, U.S. Patent No. 6,299,904.

As previously stated in Sec. VI above, in response to the Applicants' assertion that the '904 reference is not proper art, the Examiner indicated in the last paragraph of page 6 of the Office Action, that the foreign priority date of the '904 reference (5/27/97) was relied upon. As the Applicants understand it, it is *simply not possible* to rely on the foreign priority date of the cited art (pre-AIPA or post-AIPA). If the Examiner chooses to maintain the rejection, specific support in the law which would allow the use of the 5/27/97 date should be cited.

Since the '904 reference is not proper art, the teachings of the '904 reference cannot be combined with the teachings of the '339 reference and the '862 reference to render the claims obvious.

The arguments made in Sec. III above with respect to the '339 reference are hereby incorporated by reference into this section.

Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Shimizu *et al.* '339 and Kamada in view of Shimizu *et al.*, '904.

## IX. Conclusion

Reconsideration and allowance of the claims is requested in light of the amendments and arguments provided above. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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